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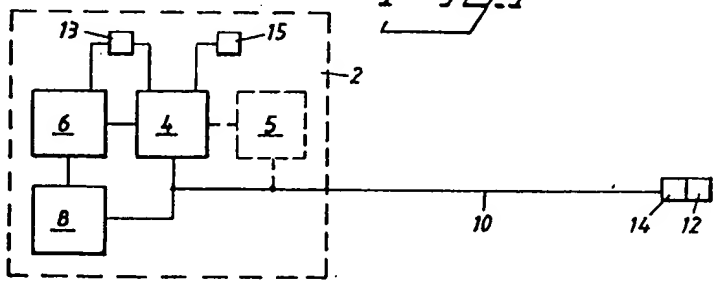
(54) Heart stimulator with ischemia detector

(57) An implantable heart stimulator comprises means (13) for setting a maximum allowable stimulation rate and an ischemia detector. Means are further connected to the ischemia detector and to this setting means for controlling said setting means to lower the maximum allowable stimulation rate in response to the detection of an ischemia.

Fig.1



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Description

Technical Field

The present invention relates to an implantable heart stimulator comprising means for setting a maximum allowable stimulation rate and an ischemia detector.

Background Art

Ischemia results from insufficient blood flow through the heart muscle. The reason therefor is blocking or passage congestion of coronary blood vessels of the heart. Blood penetration of the heart muscle is possible only in the diastolic phase, that is the phase between two consecutive contractions of the heart, when the aortic valve is closed. About 60% of the oxygen content inside the heart tissue is consumed during a heart contraction and in order to maintain the pumping efficiency of the heart the consumed oxygen must be refilled till the next contraction.

An increased heart rate results in only minor shortening of the systolic phase, that is the contraction phase of the heart, and consequently an increased heart rate results mainly in a shortening of the diastolic phase, which is the period during which oxygen is supplied to the heart as mentioned above. An increased workload will consequently worsen the situation for an ischemic patient.

In such a situation a symptomatic ischemia, that is angina pectoris, heart insufficiency or infarct, will force the patient, because of the associated pain, to stillness with a reduced heart rate as a consequence.

No heart stimulators, like pacemakers, are able to react on pain, and so called rate response pacemaker systems responding to metabolical, hemodynamical or activity inputs will try to compensate for the oxygen deficiency of the heart by increasing the stimulation rate, thus worsening the ischemic situation of the patient.

In US-A-5 199 428 a technic is described for detecting ischemia and both effecting stimulation of nerves regulating blood pressure and heart rate to reduce the heart's oxygen requirements while providing pacing therapies to maintain the patient's heart rate within acceptable limits, e.g. to overcome bradyarrhytmias and/or unphysiological AV-delays induced by the nerve stimulation.

A large portion of cardiac ischemia is silent. It has been suggested that up to 80% of ischemic heart diseases are silent, i.e. a state of ischemia which the patient is not aware of. Rate modulated pacing is used to override the poor sinoatrial response of the patient to exercise which, in this case, is physiological.

It has also been proposed heart stimulators provided with an ischemia detector to lower the actual stimulation rate in response to the detection of an ischemia to slow down or stop the further development of the ischemia, see Swedish Patent Application SE 9700182-0, filed January 23, 1997 (or corresponding PCT-application: PCT/SE98/00043, filed January 13, 1998).

In rate modulated pacing systems a programmable value sets the highest pacing rate that can be achieved in response to sensor input, the so-called maximum sensor rate (MSR). In an ischemic situation a sensor sensing e.g. the physical activity of the patient, e.g. an accelerometer, can often increase the stimulation rate, as discussed above. When a sensor in this way is controlling the pacing rate, the pacing rate will thus not exceed the programmed maximum sensor rate.

In a dual-chamber sensing and tracking pacing system in which the ventricle is stimulated with a certain delay in response to a detected atrial activity normally a programmable value sets the highest allowable ventricular pacing rate, the so-called maximum tracking rate (MTR). Conventionally these maximum sensor rate and maximum tracking rate are set so high that in an ischemic situation the pacing system can stimulate the heart to an infarct.

Disclosure of the Invention

The purpose of the present invention is to provide an implantable heart stimulator in which this disadvantage of prior art stimulators is remedied.

This purpose is obtained with a heart stimulator of the kind defined in the introductory portion having the characterizing features of claim 1.

Thus in response to the detection of an ischemia the maximum allowable stimulation rate, like the maximum sensor rate or the maximum tracking rate, is decreased. As stimulation at higher rates are most disastrous to an ischemic patient the lowering of the maximum allowable stimulation rate is an effective measure for avoiding a deterioration of an ischemia and can even improve an ischemic situation. Myocardial infarction due to inappropriately high upper rates in rate modulated pacing is consequently avoided.

The values of MSR and MTR, that are initially programmed when a stimulator is implanted, are very much dependent on the age and the status of the patient, typical values are in the ranges of 130-140/min up to 160-170/min. When an ischemia is detected the MSR/MTR are lowered to approximately 100-120/min.

According to an advantageous embodiment of the stimulator according to the invention said ischemia detector comprises ischemia analysing means for detecting an ischemia by analysis of recorded IECG:s or ECG:s. Body surface ECG diagnostics for determining ischemic states are well known and are facilitated if ventricular pacing is performed in the upper parts of the septum. In this case the depolarization is spread through the normal conduction system, e.g. the bundle branches and purkinje fibres. The evoked response will then on a surface ECG look like a normally conducted QRS and detection of an ischemia, e.g. from ST-seg-

ment elevation from a base line, is facilitated. The ECG used can suitably be a synthesized "surface" - ECG, i.e. an electrocardiogram synthesized from signals picked up by the implanted electrode. This is per se known technic, which makes an advantageous embodiment of the stimulator according to the invention possible, since no external recording equipment is needed but only already implanted means. For the same reason it is also suitable to determine an ischemia by analysing IECG:s. The technic for IECG sensing is per se well established too.

According to another advantageous embodiment of the heart stimulator according to the invention said ischemia analysing means are disposed to detect an ischemia by analysis of heart rate variability from recorded IECG:s or ECG:s. Normally heart beat intervals, AV-conduction intervals and QRS-amplitudes are subject to variations. Heart rate variation is at a maximum for a healthy individual at rest. Activity of the individual or reduced capacity due to insufficiency or illness is reflected as a decrease in the heart rate variability and this defect can be used for ischemia detection.

It is known that the heart wall is thickening and stiffening as a result of an ischemia. The accompanying change in the moving pattern of the heart wall can be detected by measuring different parameters and used for detection of an ischemic situation. Thus, according to another advantageous embodiment of the heart stimulator according to the invention, said ischemia detector comprises a lead bend sensor located at the distal end portion of the lead to be used for detection of an ischemia from the ability of the ventricle to contract and expand. Thus, with such a sensor the reduced ability of the ventricles to contract and expand can be detected as an indication of an ischemia. Alternatively, said ischemia detector comprises means for measuring the AC-impedance in the ventricle. The magnitude of the AC-impedance is a measure of the blood filling of the ventricle and consequently such an impedance measurement can be used for detecting an ischemic situation. According to still another advantageous alternative embodiment of the heart stimulator according to the invention said ischemia detector comprises means for measuring sound absorption in the heart tissue. Sound absorption is effected by changes in the stiffness of the heart tissue and the sound absorption measuring means can be provided to determine e.g. the absorption of sound ways generated at the valve closure on their way from the upper portion of the ventricle to the apex region.

As an ischemia is deteriorating the efficiency of the heart pumping an ischemic situation can be detected by studying blood pressures and cardiac outputs. Thus, according to an advantageous embodiment of the invention said ischemia detector comprises means for measuring the difference between systolic and diastolic pressures and comparing this difference obtain from one heartbeat to the difference obtain from the next heartbeat.

An ischemic state is normally associated with severe pain forcing the patient to sit down or lie down with a reduced heart rate as a consequence. At the same time the patient feels a need for forced breathing, so called hyperventilation. This unusual combination of the needs of an ischemic patient can be used for detecting the ischemia. Thus, according to yet another advantageous embodiment of the stimulator according to the invention the ischemia detector comprises patient workload sensing means and patient breathing sensing means for detecting an ischemia from the occurrence of a predetermine relation between sensed workload and sensed breathing activity.

Brief Description of the Drawings

To explain the invention more in detail as examples chosen embodiments of the heart stimulator according to the invention will be described more in detail with reference to the drawings on which

Fig. 1 is a simplified block diagram of a heart stimulator according to the invention,

Fig. 2 illustrates a pacemaker with its lead implanted in a conventional way in the right ventricle, said lead having stimulation electrodes and sensing means for the ischemia detector,

Fig. 3 and 4 show schematically a pacemaker with leads implanted in the atrium and the ventricle in a conventional way and with the ventricle lead electrode positioned in the upper parts of the septum respectively, and

Fig. 5 shows a lead bend sensor for the ischemia detector.

Description of Preferred Embodiments

Fig. 1 is a simplified block diagram of an implantable heart stimulator 2 according to the invention. The heart stimulator 2 comprises an ischemia analysis means 4 and control means 6, connected to the ischemia analysis means 4. The control means 6 are connected to a pulse generator 8 for controlling the rate of generated stimulation pulses. The pulse generator 8 in its turn is connected to a lead 10 provided with electrodes 12 at the distal end portion for delivery of stimulation pulses and possible electrical measurements, which lead 10 is intended to be implanted into the heart of a patient. Sensing means 14 for ischemia detection are also provided at the distal end portion of the lead 10 and sensing signals are supplied to the ischemia analysing means 4 through the lead 10 too.

As will be described more in detail below an ischemic state can be detected by IECG:s and ECG:s. For recording IECG:s the sensing means 14 comprise electrodes and electrical signals are supplied by the lead 10 to an recording unit 5 which in its turn is con-

nected to the ischemia analysing means 4 for further analysis of the IECG:s.

As an alternative the receiving unit 5 can be an unit for synthesizing "surface" - ECG:s from signals received from the implanted sensing means 14. In this way ECG:s are obtained which are similar to externally recorded surface ECG:s.

Setting means 13 are also provided for setting a maximum allowable stimulation rate. These setting means 13 are connected to the ischemia analysing means 4 and to the stimulation rate control means 6 such that the stored maximum allowable stimulation rate is lowered in response to the detection of an ischemia.

The maximum allowable stimulation rate remains in its lowered state for at least as long as the state of ischemia is present and possibly a predetermined period of time after the state of ischemia has terminated, e.g. 5-10 min.

An activity sensor 15 in the form of e.g. an accelerometer for sensing body movements of the patient or a sensor for sensing muscular sounds of the patient is also provided in the heart stimulator 2 and connected to the ischemia analysing means 4. Alternatively the sensor 15 can be a metabolic demand sensor for sensing metabolic changes, like changes in nutrition and oxygen consumption of the patient for controlling the stimulation rate accordingly. In this case the maximum allowable stimulation rate is equal to the maximum sensor rate. In case of dual-chamber pacing the maximum sensor rate is determining both for atrial and ventricular stimulation.

As another alternative, in dual-chamber sensing and tracking modes the sensing means 14 can be positioned in the atrium for sensing atrial activity for controlling the stimulation of the ventricle by the electrode 12. In this case the setting means 13 can be arranged to set the maximum allowable stimulation rate equal to the maximum tracking rate.

Of course the heart stimulator 2 can comprise both an activity or metabolic sensor 15 and sensing means 14 for tracking modes. Since the maximum sensor rate may be programmed lower than, equal to or greater than the maximum tracking rate the setting means 13 are in this case disposed to select the lower one of these two rates as the maximum allowable stimulation rate.

Fig. 2 shows an implanted heart stimulator in the form of a pacemaker 16, connected to the right ventricle of the heart of a patient by its lead 20. The electrode is of a bipolar type with an electrode ring 22 and a tip electrode 24 and a pressure sensor 26 is provided at a distal end portion of the lead 20 too.

Fig. 3 shows a pacemaker 32 for dual-chamber pacing and/or sensing with electrode poles 34, 36 positioned in a conventional manner in the atrium and the ventricle respectively. In case of stimulation both in the atrium and the ventricle the corresponding evoked response appearing on a (synthesized) surface ECG is shown in the same figure.

In Fig. 4 the ventricular electrode pole 36 is positioned in the upper part of the septum. This is an advantageous position of the electrode pole 36, since it will then be possible for the depolarization to propagate through the normal conduction system, e.g. the bundle branches and purkinje fibres. The evoked response will then on surface ECG:s look like normally conducted QRS, as appears from the ECG shown in Fig. 4.

For the detection of an ischemia different technics can be used. For an implantable heart stimulator an analysis of recorded IECG is a suitable method for ischemia detection, as mentioned above. The electrodes 22, 24 of the already implanted electrode lead 20, cf Fig. 2, can then be used for the recordal of the IECG. The signals received by the electrodes 22,24 can also be used for synthesizing "surface" - ECG:s to be used for detection of an ischemic state.

It is known that the heart wall is thickening and stiffening as a result of an ischemia. Thus an ischemic situation can be detected by studying changes in the moving pattern of the heart wall. In Fig. 5 a lead bend sensor 34 is shown located at the distal end portion of a lead 36. This bend sensor 34 can comprise e.g. a piezoelectric material which generates an electric signal when subject to bending movements, which signals are supplied to the ischemic analysing means 4, see Fig. 1, through conductors 38.

An ischemia can also be detected by AC-impedance measurements in the ventricle 18, as this impedance is related to the blood filling of the ventricle. For this impedance measurement the electrodes 22, 24 of the lead 20, see Fig. 2, can be used and the measurement signals are supplied to the ischemia analysing means 4 through the conductors of the lead 20. Further, an ischemia can be detected from the sound absorption in the heart tissue, as this absorption is changed with changes in the stiffness of the heart tissue. Thus, one microphone 28 is mounted at the distal end of the lead 20 and another microphone 30 is mounted on the lead 20 such that it will be positioned in the upper part of the ventricle 18 after implantation of the lead, see Fig. 2. In this way it is possible to measure the absorption of sound ways generated at the upper part of the ventricle 18 by valve closure during propagation through the ventricle 18 down to the microphone 28 situated at the ventricular bottom. The signals picked up by the microphones 28, 30 are fed to the ischemia analysing means 4 for analysis.

An ischemia can be detected by studying blood pressures and cardiac outputs too, as an ischemia will effect the efficiency of the heart pumping. Thus an ischemia can be determined by measuring the difference between the systolic and the diastolic pressures and comparing this difference from one heart beat to the difference obtained from the next heart beat. An ischemia can also be detected by monitoring the systolic pressure over time. For these pressure measure-

ments the pressure sensor 26 in Fig. 2 is used. The pressure signals obtained from the pressure sensor 26 is supplied through the lead 20 to the ischemia analysing means 4.

An ischemia can also be detected by studying the cardiac output. For this purpose a flow sensor can be positioned e.g. in the pulmonary artery for measuring the cardiac output.

An ischemia can further be detected by studying the patient workload and the patient breathing activity. The workload can be sensed by e.g. the activity sensor 15 and the breathing activity can be determined by measuring e.g. the AC-impedance between the two electrodes 22, 24 of the electrode lead 20 or between one of the electrodes 22, 24 and the case of the pacemaker 16, cf. Fig. 2. An ischemia is then detected from the occurrence of a predetermined relation between sensed workload and sensed breathing activity.

Another alternative way of detecting an ischemia consists in studying sensed repolarization of the heart and patient workload. Information about repolarization of the heart is obtained from IECG:s and ECG:s and patient workload sensing means can be formed of e.g. an activity sensor. An ischemia is then detected from the occurrence of a predetermined relation between sensed repolarization and sensed workload.

Also other technics for detecting an ischemic state are known to the man skilled in the art and it is also obvious that one or more of the above described methods for ischemia detection can be combined to obtain an improved reliability in the ischemia detection.

Claims

1. An implantable heart stimulator comprising means (13) for setting a maximum allowable stimulation rate and an ischemia detector, **characterized in** that means are connected to said ischemia detector and to said setting means (13) for controlling said setting means to lower said maximum allowable stimulation rate in response to the detection of an ischemia.

2. The stimulator according to claim 1, **characterized in** that an activity sensor (15) is provided for controlling the stimulation rate in response to sensed physical activity of the patient, said maximum allowable stimulation rate being equal to the maximum sensor rate.

3. The stimulator according to claim 1, **characterized in** that a metabolic demand sensor is provided for controlling the stimulation rate in response to sensed metabolic demand of the patient, said maximum allowable stimulation rate being equal to the maximum sensor rate.

4. The stimulator according to claim 1, said stimulator being a dual-chamber pacemaker, **characterized in** that a sensor (14,34) is provided to sense electrical activity in the atrium for controlling the ventricular stimulation rate in response thereto, said maximum allowable stimulation rate being equal to the maximum tracking rate.

5. The stimulator according to any of the claims 1 through 4, **characterized in** that said ischemia detector comprises ischemia analyzing means (4) for detecting an ischemia by analysis of recorded IECG's or ECG's.

6. The stimulator according to claim 5, **characterized in** that said ischemia analyzing means (4) are disposed to detect an ischemia by analysis of the elevation from the baseline of ST segments and T wave forms of recorded IECG's or ECG's.

7. The stimulator according to claim 5, **characterized in** that said ischemia analyzing means (4) are disposed to detect an ischemia by analysis T wave forms of recorded IECG's or ECG's.

8. The stimulator according to claim 5, **characterized in** that said ischemia analyzing means (4) are disposed to detect an ischemia by analysis of heart rate variability from recorded IECG's or ECG's.

9. The stimulator according to any of the claims 1 through 4, **characterized in** said ischemia detector comprises a lead bend sensor (34) located at the distal end portion of the lead (36) to be used for detection of an ischemia from the ability of the ventricle to contract and expand.

10. The stimulator according to any of the claims 1 through 4, **characterized in** that said ischemia detector comprises means (22,24) for measuring the AC impedance in the ventricle.

11. The stimulator according to any of the claims 1 through 4, **characterized in** that said ischemia detector comprises means (28,30) for measuring sound absorption in the heart tissue.

12. The stimulator according to any of the claims 1 through 4, **characterized in** that said ischemia detector comprises means (26) for measuring the difference between systolic and diastolic pressures and comparing this difference obtained from one heartbeat to the difference obtained from the next heartbeat.

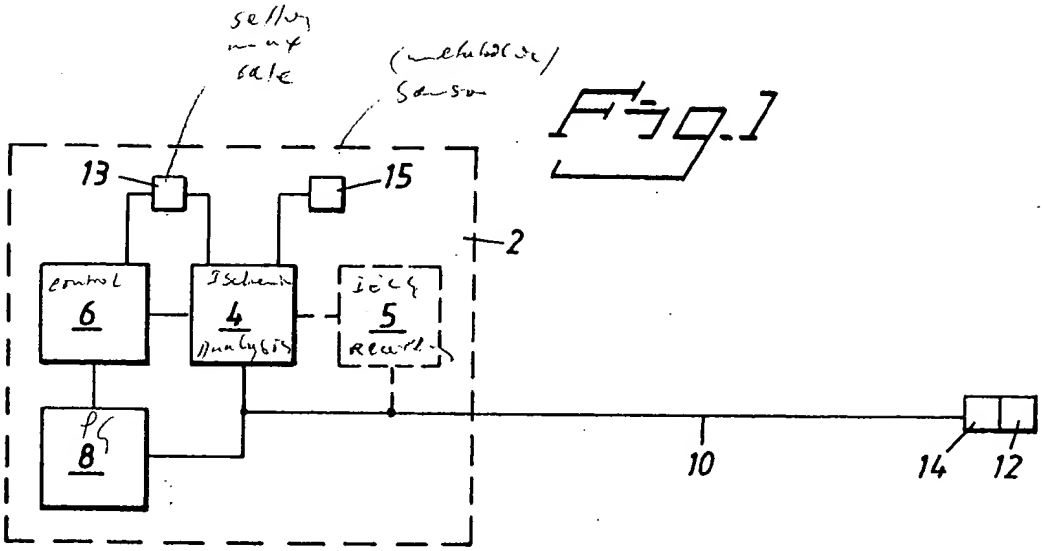
13. The stimulator according to any of the claims 1 through 4, **characterized in** that said ischemia detector comprises a flow sensor to determine cardiac output.

14. The stimulator according to any of the claims 1 through 4, **characterized in** that said ischemia detector comprises patient workload sensing means (15) and patient breathing sensing means (22,24) for detecting an ischemia from the occurrence of a predetermined relation between sensed workload and sensed breathing activity.

15. The stimulator according to any of the claims 1 through 4, **characterized in** that said ischemia detector comprises means (14) for sensing repolarization of the heart of a patient and patient workload sensing means (15) for detecting an ischemia from the occurrence of a predetermined relation between sensed repolarization and sensed workload.

16. The stimulator according to any of claims 1-15, **characterized in** that said maximum allowable stimulation rate is lowered to 100-110/min.

17. The stimulator according to any of claims 1-16, **characterized in** that said maximum allowable stimulation rate remains in its lowered state for at least as long a state of ischemia is present.


13
15
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12

Fig. 1

Fig. 2

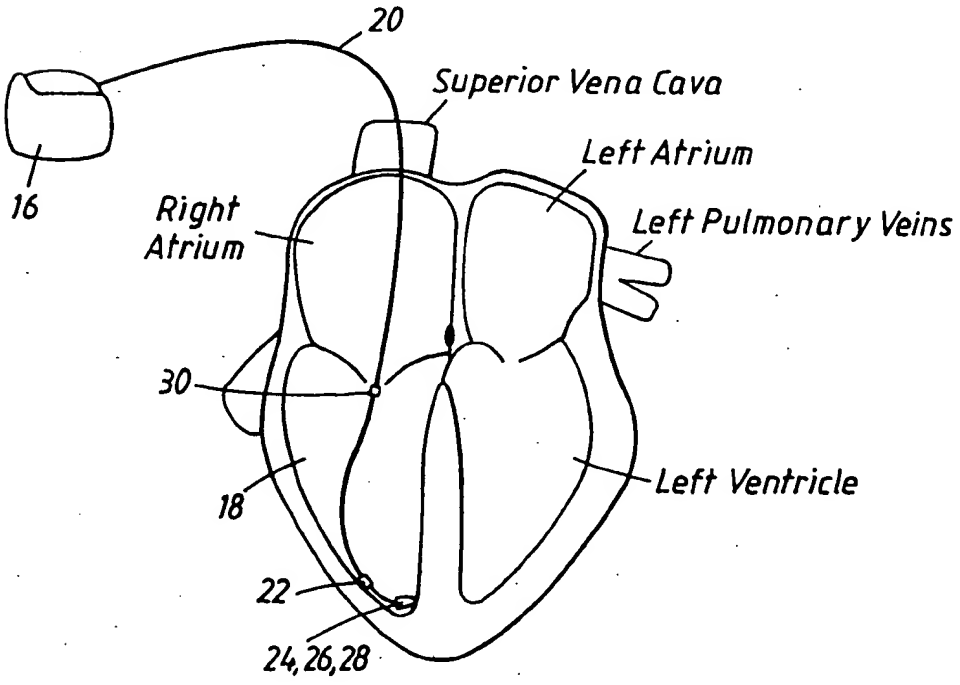

20
Superior Vena Cava
Left Atrium
16
Right Atrium
Left Pulmonary Veins
30
18
Left Ventricle
22
24,26,28

Fig.3

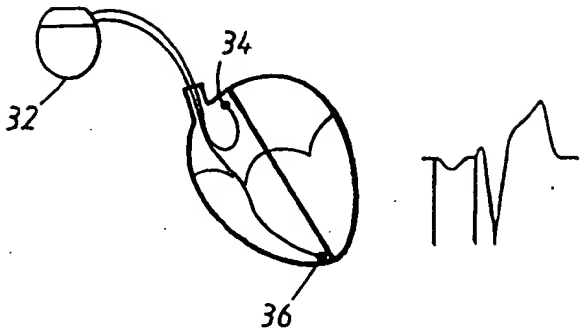


Fig.4

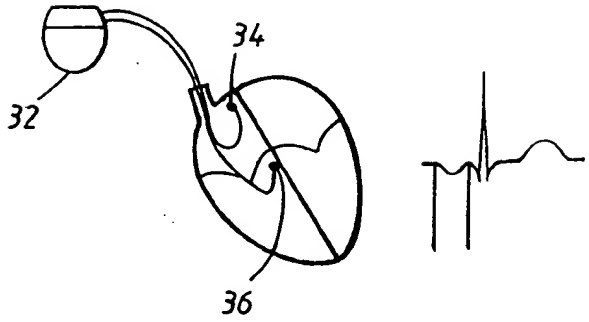
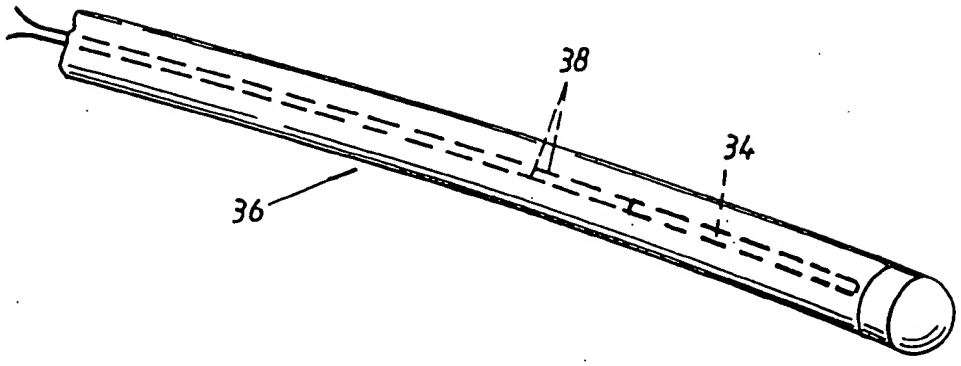


Fig.5



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EUROPEAN SEARCH REPORT

Application Number
EP 98 10 4428.2

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.6)
X	WO 9216257 A1 (MEDTRONIC, INC.), 1 October 1992 (01.10.92) * page 4, line 31 - page 5, line 3, abstract * --	1	A61N 1/365
A	EP 0108731 A1 (GRASSI, GINO), 16 May 1984 (16.05.84) * page 2, line 3 - line 8, abstract * --	1-17	
A	US 5531768 A (CLIFTON A. ALFERNESS), 2 July 1996 (02.07.96) * abstract * --	1-17	
A	EP 0545628 A2 (CARDIAC PACEMAKERS, INC.), 9 June 1993 (09.06.93) * claim 1, abstract * --	1-17	TECHNICAL FIELDS SEARCHED (Int. Cl.6) A61N A61B
A	EP 0140472 A1 (MEDTRONIC, INC.), 8 May 1985 (08.05.85) * abstract * --	1-17	
A	US 5076271 A (ANDERS LEKHOLM ET AL.), 31 December 1991 (31.12.91) * abstract * -----	1-17	

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
STOCKHOLM	23 June 1998	PATRIK BLIDEFALK

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